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s/ Julie Agozino
Julie Agozino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:
DAVID KUCERA et al.

Serial No.: 10/729,645

Confirmation No.: Not yet assigned

Filed: December 4, 2003

For: HIV PROTEASE INHIBITORS, COMPOSITIONS CONTAINING THE SAME, THEIR PHARMACEUTICAL USES AND MATERIALS FOR THEIR SYNTHESIS

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Honorable Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. § 1.97(b) or 1.97(c)

37 CFR § 1.97(b)

☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

37 CFR § 1.97(c)

☐ The Information Disclosure Statement submitted herewith is being filed after three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); after three months of the date of entry of the national stage as set forth in § 1.491 in an international application; after the mailing of a first Office Action on the merits; or after the mailing of a first Office Action after the filing of a request for continued examination under § 1.114, but before the mailing date of (1) a Final Action under § 1.113; (2) a Notice of Allowance under § 1.311; or (3) an action that otherwise closes prosecution in the application. The Commissioner is hereby authorized to charge the fee as set forth in § 1.17(p) to Deposit Account Number 500329.

☒ Applicant requests that the Examiner consider the following copending applications:

Application Serial No.	Filing Date
10/166,979	06-11-2002
10/166,957	06-11-2002
10/728,602	12-04-2003

☐ Copies of these copending applications are enclosed.

☒ Applicant hereby requests consideration of the Information Disclosure Statement, USPTO form 1449, submitted herewith. Copies of the cited references, except as noted below, are enclosed.

☒ This application is a continuation, divisional or continuation-in-part of Serial No. 10/166,979. Copies of the cited references, if not enclosed, are available in the file of the parent application or parents thereof.

☒ This application was filed after June 30, 2003, or entered U.S. national stage under 35 U.S.C. § 371, after June 30, 2003. Copies of U.S. Patents and U.S. Patent Application Publications are not enclosed. (1276 OG 55).

☐ Applicant hereby requests consideration of the enclosed International Search Report, which was received in a related international patent application.

REMARKS

In lieu of a statement of relevance or translation of the non-English documents, an English language abstract of the following documents are enclosed herewith according to M.P.E.P. § 609(III)(A3): 1) JP 8259532; 2) JP 10101654; 3) JP 2003119137; 4) WO 03/035650; and 5) WO 03/047564.

Furthermore, copies of the documents cited on Forms 1449 in the parent case, U.S. App. No. 10/166,979, are not being enclosed herein but can be found in the parent file (M.P.E.P. § 609 (I)(A)(2)).

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant(s) determine(s) that the cited document(s) do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

The Commissioner is hereby authorized to charge any fee deficiency, including any fee required under 37 C.F.R. § 1.17(p), or credit any overpayment, to Deposit Account Number 500329. A duplicate copy of this form is enclosed.

Respectfully submitted,

Date: March 29, 2004

Jeffrey H. Tidwell
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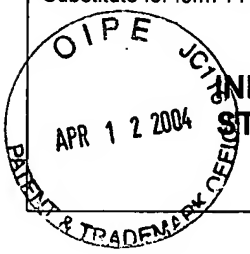

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	10/729,645
Filing Date	December 4, 2003
First Named Inventor	David John Kucera
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	PC019082B / AG 0113-02

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	Cite No. [1]	DOCUMENT NUMBER Number-Kind Code [2]	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	5629406	05-13-1997	Sankyo Company, Limited	
	AB	5,644,028	07-01-1997	Japan Energy Corporation	
	AC	2002049165	04-25-2002	Tsutomu Mimonto, et al	
	AD	6313094	11-06-2001	Japan Energy Corporation	
	AE	6329502	12-11-2001	Japan Energy Corporation	
	AF	5962640	10-05-1999	Kato, et. al.	
	AG	6222043	04-24-2001	Japan Energy Corporation	
	AH	5932550	08-03-1999	Kato, et. al.	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	Cite No. [1]	Foreign Patent Document Country Code [3] Number [4] Kind Code [5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T [6]
	AI	EP 0574135A	12-15-1993	Mimoto, et al		
	AJ	(English Abstract) JP 8259532	10-08-1996	Japan Energy Corp.		
	AK	CA 2,179,935	12-31-1996	KATO, ET AL		
	AL	AU 705193	02-06-1997	Japan Energy Corporation		
	AM	JP 10-867489	04-07-1998	Yabe, et al		X
	AN	(English Abstract) JP 10101654	04-21-1998	Japan Energy Corp.		

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	AO	WO 2002100844	12-19-2002	Agouron Pharmaceuticals, Inc.		
	AP	(English Abstract) JP 2003119137	04-23-2003	Nakamura, et al		
	AQ	WO 03/035076	05-01-2003	Di Francesco, et al		
	AR	(English Abstract) WO 03/035650 A1	05-01-2003	Kawano, et al		
	AS	WO 03/049690	06-19-2003	Walker, et al		
	AT	WO 03/062238	07-31-2003	Tarby, et al		
	AU	WO 03/062204	07-31-2003	Egbertso, et al		
	AV	(English Abstract) WO 03/047564	12-06-2003	Mu-Rai, et al		
	AW	WO 2002 100845	12/19/2002	Agouron Pharmaceuticals, Inc.		
	AX	EP 0751145 A2	06-28-1996	Japan Energy Corp.		
	AY	EP 0490667	06-17-1992	Japan Energy Corp.		
	AZ	WO 93/13066	07-08-1993	Syntex		
	BA	EP 0498680	08-12-1992	Sankyo Company Ltd.		
	BB	EP 0706794	04-17-1996			

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

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	BC	ANDRÉS, "Stereoselective Cyanation Of Chiral α-Amino Aldehydes By Reaction With Nagata's Reagent: A Route To Enantiopure β-Amino-α-Hydroxy Acids," *Tetrahedron Asymm.*, 2001, pp. 347-353, vol. 12.	
	BD	BLANCO, M. et al., "Enantiospecific And Stereoselective Synthesis Of Polyhydroxylated Pyrrolidines And Indolizidines From *Trans*-4-Hydroxy-L-Proline," *J. Org. Chem.* 1996, pp. 4748-4755, vol. 61.	
	BE	HUMPHREY, J. et al., "Chemical Synthesis Of Natural Product Peptides: Coupling Methods For The Incorporation Of Noncoded Amino Acids Into Peptides," *Chemical Reviews,* 1997, 2243-2266 vol. 97.	
	BF	IKUNAKA, et. al., "A Concise Synthesis of (2S,3S)-BocAHPBA and ®-BocDMTA, Chiral Building Blocks for Peptide-Mimetic HIV Protease Inhibitors," *Tetrahedron Asymm*etry, 2002, Vol. 13, 1201.	
	BG	JACQUES, et al., Enantiomers, Racemates, and Resolutions, 1981, John Wiley & Sons, New York.	
	BH	LAROCK, et al., Comprehensive Organic Transformations, 1989, Chapter 9, New York	
	BI	SASAI, H., et al., "Diastereoselective Catalytic Asymmetric Nitroaldol Reaction Utilizing Rare Earth-Li-(*R*)-BINOL Complex. A Highly Efficient Synthesis Of Norstatine," *Tetrahedron Letters,* 1994, pp. 6123-6126, vol. 35, no. 33.	
	BJ	SHARMA, R. et al., "Regioselective Enolization And Alkylation Of 4-Oxo-*N*-(9-Phenylfluoren-9-yl)Proline: Synthesis Of Enantiopure Proline-Valine And Hydroxyproline-Valine Chimeras," *J. Org Chem.* 1996, pp. 202-209, vol. 61.	
	BK	SUSTMANN, et al., Comprehensive Organic Synthesis, 1991, Vol. 6, 301-434, Trost.	
	BL	BELL, et al., "Development of Orally Active Oxytocin Antagonists: on 1-(1-{4-[1-2- Methyl-1-oxidophyridin-3-ylmethyl)piperidin-4-yloxy]-2-methoxybenzoyl}peperidin-5-yl)-1-4-dihydrobenz[d][1,3]oxazin-2-one (L-372,662) and Related Pyridines," *Journal of Medicinal Chemistry*,1998, 2146-2163, Vol 41.	
	BM	YOSHIAKI, Patent Abstracts of Japan, Publication No. 10182601, 1998, No. 12.	
	BN	SHEHA, et al., *Euro J. Med. Chem.*, 2000, 887-894, Vol. 35, No. 10.	

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	BO	KITZAKI, et al., *Chem & Pharm. Bulletin*, Pharm. Soc. Of Japan, 1994, 2636-2640, Vol. 42, No. 12.	
	BP	SLEE, et al., *J.A.C.S.*, 1995, 11867-11878, Vol., 117, No. 48.	
	BQ	KOMAI, et al., *Biorg. Med. Chem.*, 1996, 1356-1377, Volo. 4, No. 8.	
	BR	KISO., et al., *Arch. Pharm.*, Pharm. Med. Chem., 1998, 87-89, Vol. 331.	
	BS	MATSUMOTO, et al., *Biorg. Med. Chem.*, 2001, 417-430, Vol. 9, No. 2.	
	BT	TAM, et. al., *J. Med. Chem.*, 1992, 1318-1320, Vol. 35, No. 7.	
	BU	VAN-DUC LE, et. al., "Structure-Activity of FIV and HIV Protease Inhibitors Containing Allophenylnorstatine," *Biorg. Med. Chem.*, 2001, 1185-1195, Vol. 9.	
	BV	MIMOTO, et al., "Structure-Activity Relationship of Orally Potent Tripeptide-Based HIV Protease Inhibitors containing HydroxymethylCarbonyl Isotease," *Chem & Pharm. Bulletin*, Pharm Soc. Of Japan, 2000, 1310-1326, Vol. 48, No. 9.	
	BW	SODERGREN, et. al., "Allylic Alcohols Via Catalytic Asymmetric Expoxide Rearrangement," *J. Am. Chem. Soc.*, 2000, 6610-6018, Vol. 122, No. 28.	
	BX	FALORNI, et. al., "Optically Active 4-Oxaproline Deriviatives: New Useful Chiral Lsynthons Derived from Serine and Threonine," Tetrahedron: Asymmetry, 1995, 287294, Vol. 6, No. 1.	
	BY	BOBBITT, et. al., "Synthesis of Isoquinoline Alkaloids. II. The synthesis and Reasctions of 4-Methyl-3-pyridinecarboxaldehyde and Other 4-methyl-3-substituted Pyridines," J. Org. Chem., 1959, 560, Vol. 25.	
	BZ	BUNDGAARD, Design of Prodrugs, 1985.	
	CA	CARLSEN, et. al., "Thermolysis of *N*-Allylic 1,2,4-Triazoles," *Institute of Organic Chemistry*, 1997, 797-805, Vol. 34.	

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	CB	CHARLESWORTH, et. al., "Phthalide Formation," *Can. J. Chem.*, 1963, 1071-1077, Vol. 41.	
	CC	DEMANGE, et. al., "Practical Synthesis of Boc and Fmoc Protected 4-Fluoro and 4-Difluoroprolines from *Trans*-4-Hydrozyproline," *Tetrahedron Letters*, 1998, 1169-1172, Vol. 39.	
	CD	DONDONI., et. al., "Total Synthesis of (+)-Galactostatin. An Illustration of the Utility of the Thizole-Aldehyde Synthesis," *J. Org. Chem..*, 1995, 4749-4754, Vol. 60.	
	CE	Enantiomers, Racemates, and Resolutions, 1991.	
	CF	FUJIWARA, et. al., "Orientation in Nitration and Sulfonation of 2,5-Dimethylbenzoic Acid," *Can. J. Chem.*, 1970, 1346-1349, Vol. 48.	
	CG	HARADA, et. al., "Synthesis and Resolution of –*N*-[1-methyl-4(3-methylbenzyl)hexahydro-1*H*-1,4-*diazepin-6-yl*]-*1*H-indazole-3-Carboxamide By Preferential Crystallization," *Tetrahedron Asymmetry*, 1997, 2367-2374, Vol.8, No. 14.	
	CH	HOLZGRABE, U., "Cer(IV)sulfat-Oxidationen: Intramolekulare Cyclisierung von N-benzyl-β-Aminoketonen zu 4-Benzoyl-1,2,3,4-tetrahydro-isochinolinen," *Arch. Pharm.* 1987, 647-654, Vol. 320.	
	CI	HUANG, et. al., "The Improved Preparation of 7,8-Dihydro-Quinoline-596*H*)-One And 6,7-Dihydro-*5H-1*-Pyrindin-5-One," *Synthetic Communications*, 1998, 1197-1200, Vol. 28, No. 7.	
	CJ	HURSTHOUSE, et. al., "Reactions of Ethyl 2-acetyl-2-azabicyclo[2.2.1]Hept-5-ene-3-Carboxylate and 4-acetylamino-2-oxabicyclo[3.3.o]oct-7-en-3-one With Some Electrophiles," *J. Chem. Soc.,* 1995, 2419-2425, Vol. 1.	
	CK	KARANEWSKY, et. al., "Phosphinyloxy)acyl Amino Acid Inhibitors of Angiotensin Converting Enzyme," *J. Med. Chem.*, 1990,1459-1469, Vol. 33.	
	CL	LUDEMAN, et. al., "Synthesis and Antitumor Activity of Cyclophosphamide Analogs. 1. Benzo Annulated Cyclophosphamide and Related Systesm," Journal of Medicinal Chemistry, 1975, 1251, Vol. 18, No. 12.	
	CM	MATAYOSHI, et. al., "Novel Fluorogenic Substrates For Assaying Retroviral Proteses by Resonance Engergy Transfer," *Science*, 1990, 954-958, Vol. 247.	
	CN	MILLER, et. al., "Preparation of Crystalline Diphenyldiazomethane," *J. Org. Chem.*, 1958, 560-561, Vol. 24.	

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	CO	MIMOTO, et. al., "Structure-Activity Relationship of Small-Sized HIV Protease Inhibitors Containing Allophenylnorstatine," *J. Med. Chem.*, 1999, 1789-1802, Vol. 42.	
	CP	NAGASAWA, et. al., "β-Substituted Cysteines as Sequestering Agents for Ethanol-Derived Acetaldehyde in Vivo," *J. Med. Chem.*, 1987, 1373, Vol. 30.	
	CQ	NUSSBAUMER, et. al., "Synthesis and Structure-Activity Relationships of Benzo[*b*]thienylallylamine Antimycotics," *Med. Chem.*, 1991, 65-73, Vol. 34.	
	CR	O'BRIEN, et. al., "Inhibotors of Acyl-CoA:Cholesterol)-Acyl Transferase (ACAT) as Hypocholesterolemic Agents. Incorporation of Amide or Amine Funtionalities into a Series of Disubstituted Ureas and Carbamates. Effects on ACAT Inhibition in Vitro and Efficacy In Vivo," *J. Med. Chem.*, 1994, 1810-1822, Vol. 37.	
	CS	ONDA, et. al., "Structure of Carzinophilin. II. A New Amino Acid and Its Derivative Form Carzinophillin," *Chem. Pharm. Bull.*, 1971, 2013-2019, Vol 19, No. 10.	
	CT	PAUWELS, ET. AL., "rapid and Automated Tetrazolium-Based Colorimetric Assay for the Detetion of Anti-HIV Compounds," *Journal of Virological Methods*, 1988, 309-321, Vol. 20.	
	CU	PETROPOULOS, et. al., "a novel Phenotypic Drug Susceptibility Assay for Human Immunodeficiency Virus type 1," *Antimicrob Agents Chemother*, 2000, 920-928, Vol. 44, No. 4.	
	CV	Protective Groups in Organic Synthesis, 3rd Edition, 1999.	
	CW	WEISLOW, et. al., "New Soluble-Formazan Assay for HIV-1 Cytopathic Effects: Applicatin to High-Flux for AIDS-Antiviral Activity," *Journal of the National Cancer Institute*, 1989, 577-586, Vol. 18, No. 8.	
	CX	WIPF, et. al., "SN2'-Reactions of Peptide Aziridines. A Cuprate-Based Approach to (*E*)-Alkene Isosteres," *J. Org. Chem.*, 1994, 4875-4886, Vol. 59.	
	CY	YOSHIMURA, et. al., "JE-2147: A Dipeptide Protease Inhibitor (PI) that Potently Inhibits Multi-PH-Resistant HIV-1," Proc. Natl. Acad. Sci. USA, July 1999, 8675-8680, Vol. 96.	

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